

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BAUSCH HEALTH IRELAND LIMITED and  
SALIX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

CIVIL ACTION NO. 1:22CV20  
c/w 1:22CV85  
(JUDGE KLEEHE)

MYLAN PHARMACEUTICALS INC.,

Defendant.

MEMORANDUM OPINION AND ORDER DENYING PLAINTIFFS'  
MOTIONS TO STRIKE AFFIRMATIVE DEFENSES AND FOR JUDGMENT ON  
THE PLEADINGS [1:22CV20, ECF NO. 103; 1:22CV85, ECF NO. 7]  
AND MOTION TO FILE SUPPLEMENTAL BRIEFING [ECF NO. 151]

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This patent infringement case involves several United States Patents (collectively, the "patents-in-suit"),<sup>1</sup> owned by the plaintiffs, Bausch Health Ireland Limited ("Bausch") and Salix Pharmaceuticals, Inc. ("Salix") (collectively, "the Plaintiffs") [ECF No. 91].<sup>2</sup> The pharmaceutical composition and methods described in these patents are used to produce Trulance®, a drug indicated for the treatment of chronic idiopathic constipation ("CIC") and irritable bowel syndrome with constipation ("IBS-C"). Id. at 3-5. The Plaintiffs allege that the defendant, Mylan

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<sup>1</sup> The patents-in-suit are United States Patent Nos. 7,041,786 ("the '786 patent"), 9,610,321 ("the '321 patent"), 9,616,097 ("the '097 patent"), 9,919,024 ("the '024 patent"), 9,925,231 ("the '231 patent"), 10,011,637 ("the '637 patent"), 11,142,549 ("the '549 patent"), and 11,319,346 ("the '346 patent") [1:22CV20, ECF No. 91 at 2; 1:22CV85, ECF No. 1].

<sup>2</sup> All docket numbers refer to Civil Action No. 1:22CV20 unless otherwise noted.

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Pharmaceuticals Inc. ("Mylan"), has infringed the patents-in-suit by seeking approval to manufacture and sell generic versions of Trulance®.

Pending is the Plaintiffs' motion invoking Federal Rule of Civil Procedure 12 [1:22CV20, ECF No. 103; 1:22CV85, ECF No. 7]. They ask the Court to grant them judgment on the pleadings as to Mylan's infringement of the patents-in-suit, to dismiss Mylan's invalidity counterclaims, and to strike Mylan's invalidity affirmative defenses. Id. Also pending is the Plaintiffs' motion to supplement their briefing on these issues [ECF No. 151]. For the reasons that follow, the Court **DENIES** their motions.

**I. Background**

In this Hatch-Waxman suit, the Plaintiffs allege that Mylan has infringed the patents-in-suit [ECF No. 91 at 5-10]. Salix, a division of Bausch holds approved New Drug Application No. 208745, under which the United States Food and Drug Administration ("FDA") granted approval on January 19, 2017 for 3mg plecanatide oral tablets, marketed under the trade name Trulance®. Id. at 2-3, 5. The patents-in-suit are listed in the FDA's Orange Book, Approved Drug Products with Therapeutic Equivalence Evaluations, for Trulance®. Id. These patents fall into three patent families. Family 1 includes the '786 patent, which discloses and claims the

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active pharmaceutical ingredient, plecanatide [ECF No. 104 at 3].

Family 2 includes the '321 patent, the '097 patent, the '024 patent, and the '231 patent, which disclose and claim formulations of plecanatide and methods of treating constipation using such formulations. Id. Family 3 includes the '637 patent, which discloses and claims purified plecanatide. Id.

On March 18, 2021, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Mylan notified the Plaintiffs through a Paragraph IV letter that it had filed Abbreviated New Drug Application No. 215686, seeking FDA approval to manufacture and sell generic plecanatide oral tablets prior to the expiration of the patents-in-suit [ECF No. 104-1]. Thereafter, on April 28, 2021, in the District of New Jersey, the Plaintiffs filed suit against Mylan and several of its related entities alleging infringement. Id. On March 8, 2022, the New Jersey court granted Mylan's motion to dismiss its related entities as defendants and sustained Mylan's venue challenge, transferring the case to this Court [ECF No. 56].

On May 5, 2022, the Plaintiffs filed an amended complaint, removing the dismissed defendants [ECF No. 91]. Mylan timely answered and filed counterclaims contesting the validity of the patents-in-suit [ECF No. 99]. Thereafter, the Plaintiffs filed

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their pending Rule 12 motion [ECF No. 103]. Mylan then amended its answer and counterclaim as a matter of course [ECF No. 111].

## **II. Standards of Review**

### **A. Rule of Civil Procedure 12(c)**

Federal Rule of Civil Procedure 12(c) provides that, “[a]fter the pleadings are closed - but early enough not to delay trial - a party may move for judgment on the pleadings.” “The standard of review for Rule 12(c) motions is the same as that under Rule 12(b) (6).” Drager v. PLIVA USA, Inc., 741 F.3d 470, 474 (4th Cir. 2014) (citation omitted)). The only difference between a Rule 12(c) motion and a Rule 12(b) (6) motion is timing. See Burbach Broad. Co. of Del. v. Elkins Radio Corp., 278 F.3d 401, 405-06 (4th Cir. 2002).

A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b) (6) on the ground that it does not state a claim upon which relief may be granted. When reviewing the sufficiency of a complaint, the district court “must accept as true all of the factual allegations contained in the complaint.” Anderson v. Sara Lee Corp., 508 F.3d 181, 188 (4th Cir. 2007) (quoting Erickson v. Pardus, 551 U.S. 89, 94 (2007)). “While a complaint . . . does not need detailed factual allegations, a plaintiff’s obligation to provide the ‘grounds’ of his

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'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp v. Twombly, 550 U.S. 544, 555 (2007) (citation omitted). A court is "not bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986). To be sufficient, "a complaint must contain 'enough facts to state a claim to relief that is plausible on its face.'" Anderson, 508 F.3d at 188 n.7 (quoting Twombly, 550 U.S. at 547). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

In resolving a motion to dismiss for failure to state a claim, the court may consider documents that are "explicitly incorporated into the complaint by reference and those attached to the complaint as exhibits" without converting it to a motion for summary judgment. Goldfarb v. Mayor & City Council of Baltimore, 791 F.3d 500, 508 (4th Cir. 2015). A motion to dismiss "does not resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." Republican Party of N.C. v. Martin, 980 F.2d 943, 952 (4th Cir. 1992).

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**B. Rule of Civil Procedure 12(f)**

Federal Rule of Civil Procedure 12(f) permits a court, on motion of a party, to strike from any pleading "an insufficient defense." In the Fourth Circuit, "Rule 12(f) motions are generally viewed with disfavor 'because striking a portion of a pleading is a drastic remedy and because it is often sought by the movant simply as a dilatory tactic.'" Waste Mgmt. Holdings, Inc. v. Gilmore, 252 F.3d 316, 347 (4th Cir. 2001) (citing 5A A. Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 1380, 647 (2d ed. 1990)). "Nevertheless, a defense that might confuse the issues in the case and would not, under the facts alleged, constitute a valid defense to the action can and should be deleted." Id.

**III. Discussion**

**A. Judgment on the Pleadings as to the Plaintiffs' Infringement Claims**

The Plaintiffs allege that Mylan has infringed the patents-in-suit by filing its ANDA and seeking approval to sell generic forms of Trulance®. In their pending motion, the Plaintiffs now contend that they are entitled to judgment on the pleadings as to these claims. But, because Mylan denies all infringement

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allegations in its answer, judgment on the pleadings is not warranted. See Republican Party of N.C., 980 F.2d at 952 (noting that a Rule 12 motion does not resolve contests surrounding the merits of a claim).

According to the Plaintiffs, judgment on the pleadings is appropriate despite Mylan's denials because Mylan cannot deviate from the defenses asserted in its Paragraph IV notice letter, which did not include non-infringement arguments for every asserted claim of the patents-in-suit [ECF No. 104 at 6-9]. Mylan, on the other hand, asserts that its notice did address infringement of the asserted claims and, even if the notice had not, it is not limited to the defenses identified therein [ECF No. 111 at 13-15].

Pursuant to the Hatch-Waxman Act, a generic drug manufacturer submitting an ANDA must certify, among other things, that the patents associated with the drug are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii). The generic must also send a "Paragraph IV notice letter" to the patent holder that includes "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Id. at § 355(j)(2)(B)(iv)(II).

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Although required by statute, the Federal Circuit has held that the Paragraph IV notice requirement "cannot be enforced by a private party in a patent infringement action." Minnesota Mining & Mfg. Co v. Barr Labs., Inc., 289 F.3d 775, 777 (Fed. Cir. 2002); see also Abbott Lab'ys v. Lupin Ltd., 2011 WL 1897322, at \*7 (D. Del. May 19, 2011) ("The Court has no authority to penalize deficiencies in Paragraph IV notice letters; the Hatch-Waxman Act creates no private cause of action for such notice letter shortcomings."). District courts applying this holding have found that generic ANDA filers are not limited to the theories raised in their paragraph IV letters in Hatch-Waxman litigation. See e.g., Abbott, 2011 WL 1897322, at \*7; Abbott Lab'ys, Inc. v. Apotex Inc., 725 F. Supp. 2d 724, 728 (N.D. Ill. 2010) (collecting cases).

This Court agrees. Because it possesses no authority to penalize any perceived deficiencies in Mylan's Paragraph IV notice letter under the Hatch-Waxman Act, it will not limit Mylan to the theories raised in therein. Mylan may develop its non-infringement contentions in the ordinary course of this litigation and the Court denies the Plaintiffs' motion for judgment on the pleadings as to its infringement claims.



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**B. Judgment on the Pleadings as to Mylan's Invalidity Counterclaims**

Next, in its counterclaim, Mylan challenges the validity of the patents-in-suit. The Plaintiffs argue that they should be granted judgment on the pleadings because Mylan's counterclaims lack factual support. Although Mylan disagrees that its pleading was deficient, it amended its counterclaims as a matter of course on June 29, 2022, adding factual support for its invalidity arguments [ECF No. 111].

This amendment renders the Plaintiffs' motion on the counterclaims moot. Even so, in light of the factual allegations in Mylan's amended counterclaim, the Court cannot find that it has failed to state a claim upon which relief can be granted. For these reasons, the Court denies the Plaintiffs' motion for judgment on the pleadings as to Mylan's invalidity counterclaims.

**C. Motion to Strike Mylan's Affirmative Defenses**

Mylan also asserts invalidity as an affirmative defense to the Plaintiffs' infringement claims. In their pending motion, the Plaintiffs ask the Court to strike these defenses from Mylan's answer because they lack factual support to satisfy the plausibility pleading standard. Mylan oppose their motion, contending that the heightened pleading standard does not apply to

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affirmative defenses and that their pleading should not be stricken because the Plaintiffs had fair notice of their defenses.

Pursuant to Federal Rule of Civil Procedure 12(f), a court may strike an insufficient defense from a pleading. While some district courts in the Fourth Circuit have held that the plausibility pleading standard applies to affirmative defenses, neither the Supreme Court of the United States nor the Fourth Circuit Court of Appeals has addressed this issue. The Fourth Circuit has instructed, however, that Rule 12(f) motions are generally viewed with disfavor, Waste Mgmt., 252 F.3d at 347, and that “[a]n affirmative defense may be pleaded in general terms and will be held to be sufficient ... as long as it gives plaintiff fair notice of the nature of the defense.” Clem v. Corbeau, 98 F. App'x 197, 204 (4th Cir. 2004) (quotation and citation omitted).

To determine whether Mylan's affirmative defenses have been sufficiently pleaded, the Court applies Federal Rule of Civil Procedure 8. Rule 8(b) requires that a party, in responding to a pleading, must “state in short and plain terms its defenses to each claim asserted against it; and admit or deny the allegations asserted against it by an opposing party.” Rule 8(c) requires that a party, in responding to a pleading, must “affirmatively state any avoidance or affirmative defense.”

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Here, Mylan's affirmative defenses are supported by the facts alleged in its answer and counterclaim and, thus, satisfy the standards set forth in Rule 8. The Court also finds that the Plaintiffs had fair notice of the nature of Mylan's invalidity affirmative defenses based on the facts alleged in Mylan's counterclaim as well as its Paragraph VI notice letter. "Further, even if the Court concluded the statutory pleadings alone were insufficient under Rule 8(a), this Court requires prompt disclosure of invalidity contentions, which militates against dismissal of insufficient invalidity counterclaims." Palmetto Pharms. LLC v. AstraZeneca Pharms. LP, 2012 WL 6025756, at \*6 (D.S.C. Nov. 6, 2012) (holding the defendant's affirmative defense of invalidity was sufficiently pled under Rule 8(c)). The Court therefore denies the Plaintiffs' motion to strike Mylan's affirmative defenses.

**D. Motion to Supplement Briefing**

On January 13, 2023, the Plaintiffs moved for leave to supplement their briefing in support of their Rule 12 motion [ECF No. 151]. Specifically, they wish to add argument related to recent rulings of the United States Patent Trial and Appeal Board ("PTAB") relating to inter partes review ("IPR") proceedings involving four of the patents-in-suit. Id. Mylan opposes their

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motion, asserting that any decision of the PTAB is irrelevant to the pending motion [ECF No. 155]. The Court agrees. Because supplemental briefing would not aid its decision-making process or alter its conclusion, the Court **DENIES** the Plaintiffs' request.

**IV. Conclusion**

For the reasons discussed, the Court **DENIES** the Plaintiffs' motions to strike affirmative defenses and for judgment on the pleadings [1:22CV20, ECF No. 103; 1:22CV85, ECF No. 7]. It also **DENIES** the Plaintiffs' motion to supplement their briefing [ECF No. 151].

It is so **ORDERED**.

The Clerk shall transmit copies of this Order to counsel of record by electronic means.

Dated: March 30, 2023



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THOMAS S. KLEEH, CHIEF JUDGE  
NORTHERN DISTRICT OF WEST VIRGINIA